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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,678	01/18/2002	Y. Tom Tang	PF-0595 USN	7571

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EXAMINER	
SCHNIZER, HOLLY G	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,678	TANG ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicants election of Group II, claims 3-4, 9-10, and 13-14 with traverse in the Response filed May 10, 2004 is acknowledged. Upon reconsideration, the examiner has rejoined Groups I-IV, claims 1-4 and 6-15. Applicant argues that all claims 1-20 with regard to SEQ ID NOs: 6 (protein encoded by SEQ ID NO:12) and 12 (polynucleotide) should be rejoined. Applicants argue that Groups V, VI, and VII drawn to an antibody, an agonist, and an antagonist of the polypeptide of Group I, respectively, should be examined along with the polypeptide and polynucleotide since the claims of these groups are dependent from the claims of Group I and are also drawn to products. This argument has been considered but is not deemed persuasive because the polypeptide of Group I has a different structure, properties, and function from the antibody, the agonist, and the antagonist of Groups V-VII and therefore they are not considered to share a common special technical feature. Applicants argue that Groups VIII and IX should be rejoined because they are drawn to methods of using the product of Group I and therefore are technically interrelated. This argument has been considered but is not deemed persuasive because pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited inventions of each of the other categories related thereto. Accordingly, the main invention (Group I as rejoined) comprises the first-recited product, the polynucleotide encoding the polypeptide, a recombinant vector, a host cell, and the

encoded polypeptide, methods of making the polypeptide using the polynucleotide, and methods of using the polynucleotide in hybridization techniques. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The Restriction Requirement is still deemed proper and is thus made FINAL.

Status of the Claims

Claims 1-4 and 6-20 are pending. Claims 1-4 and 6-15 as they pertain to SEQ ID NOs: 6 and 12 have been rejoined and will be examined on the merits. Claims 16-20 are withdrawn from consideration as being drawn to non-elected subject matter.

Priority

The present application claims priority to three provisional applications. However, support for the polynucleotide of SEQ ID NO: 12 and polypeptide of SEQ ID NO:6 was found only in 60/172,232. Therefore, the effective filing date of the present application with respect to claims concerning polynucleotides and polypeptides of SEQ ID NOs: 12 and 6, respectively, is considered to be April 19, 1999.

Specification

The Specification is objected to for reference to the attorney docket number instead of the U.S. application serial number on page 40, lines 31-34.

Claim Objections

Claims 1-4 and 6-20 are objected to because of the following informalities: The claims encompass polypeptides of SEQ ID NOs: 1-5 and polynucleotides of SEQ ID NOs: 7-11 and methods of making and using them which are part of a non-elected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 6-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. Since specific and substantial utility has not been found, credibility has not been assessed.

The claims are drawn to polypeptides of SEQ ID NO:6 and polynucleotides encoding SEQ ID NO:6, vectors, host cells, methods of making the polypeptides, and methods of using the polynucleotides in a hybridization assay. The Specification indicates that the protein (SEQ ID NO: 6) encoded by SEQ ID NO:12 is a heat shock protein. There is no further guidance with regard to the activity of the claimed protein or its relationship to any disease or disorder.

The Specification asserts that the polynucleotides and proteins of the present invention have specific utilities including methods of treatment; diagnosis; identification of genetic variants, mutations, and polymorphisms; making antibodies; and making

hybridization probes to map the naturally occurring genomic sequence on the chromosome.

There appears to be no well-established utility for the claimed proteins or polypeptides or polynucleotides that encode them.

The asserted utilities that the claimed polynucleotides and polypeptides could be used in methods of treatment or diagnosis do not appear to be substantial. On page 26-27, the Specification lists over 200 diseases or disorders that the claimed polypeptides and polynucleotides could be used to treat in the cases that the disorder is associated with decreased expression of the polypeptide. The diseases and disorders disclosed occur in different tissues and by unique mechanisms of pathogenesis. On page 27, lines 29-33, the Specification indicates that the same diseases and disorders could be treated with an antagonist of the polypeptide if the diseases and disorders are associated with increased expression of the protein. However, the Specification does not provide guidance as to how the polypeptides and/or polynucleotides of the present invention are associated with any disease. Which diseases or disorders could be successfully treated by administering the protein of the present invention and which could be treated by administering an antagonist of the protein of the present invention and what is the identity of that antagonist? With respect to diagnosis, what would one look for to diagnose any of the indicated diseases—increased expression, decreased expression, polypeptide mutations, deletions? Thus, the assertions that the claimed polynucleotides and polypeptides can be used to treat the diseases is not considered substantial because it would require carrying out further research to identify which of the

listed diseases are associated with decreased expression of the claimed polypeptide and could be treated by administering the polypeptide and which of the diseases are associated with increased expression of the claimed polypeptide and could be treated by administering an antagonist or antibody to the claimed polypeptide.

The assertion that the polynucleotides of the invention could be used to map the naturally occurring genomic sequence is not considered a substantial utility because it amounts to basic research of the properties of the claimed product itself. Moreover, an assertion that the claimed polynucleotide could be used to map the chromosome is not considered specific in the absence of a specific DNA target

The assertion that the polynucleotides of the invention could be used to identify genetic variants, mutations, or polymorphisms is not considered a substantial utility because there is no guidance that would allow such identification. Further research would be required to reasonably identify how the polynucleotides could be used in such assays. Moreover, since the Specification does not provide guidance regarding any genetic variants, mutations, or polymorphisms of the claimed polynucleotide, such a method of identifying such mutations is not considered a substantial utility because it amounts to a method of studying the product itself or a method of identifying a material that itself has no specific or substantial utility.

The assertion that the claimed polynucleotides could be used to screen libraries or in methods of making proteins or methods of making antibodies are not considered substantial utilities because, as explained above, the Specification does not provide any asserted utility for the claimed polynucleotides or those close in sequence that would be

found in such a screening assay. Likewise, the asserted utility amounts to a method of assaying or identifying a material that itself has not specific or substantial utility (see Utility Guidelines Training Materials available at www.USPTO.gov, p. 6).

The methods of Claims 7 and 8 are not considered to have substantial utility because they involve detecting polynucleotides that hybridize to the claimed polynucleotides and the Specification has not asserted a utility for the claimed polynucleotides or any polynucleotides that hybridize thereto that is specific and substantial. Thus, the methods of Claim 7 and 8 are considered methods of identifying a material that itself has no specific or substantial utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-4 and 6-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In addition, Claims 1-4, 6, 9-13, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Even in the case that the claimed polynucleotides, vectors, host cells, and polypeptides were shown to be supported by a specific and substantial utility, the Specification does not provide support for using the claimed products in any methods of treatment or diagnosis or methods of screening for drugs. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d, 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include (1) quantity of experimentation, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The nature of the invention involves the isolation of a cDNA molecule from a library that encodes a protein that has sequence identity to heat shock proteins. The Specification discloses six unique polynucleotide sequences encoding six unique polypeptides. A search of the sequence databases indicates that the claimed protein has a sequence homologous with a DNAJ domain. However, at the time of the invention, eukaryotic homologues of proteins in the dnaJ family were known to have diverse function and the family of proteins was not well characterized (Caplan et al. Mol. Biol. Cell (1993) 4: 555-563). The Specification does not specifically disclose the activity of the protein of SEQ ID NO:6 but implies that it is a heat shock protein. Thus, it appears that the proteins encoded by the polynucleotides of the claimed invention were

unknown and that using the claimed polynucleotides would require characterization of the role and relationship of the encoded protein to any disease or disorder in order to use the claimed polynucleotides in any method of treatment, diagnosis or drug screening.

The Specification only provides general guidance as to how polynucleotides disclosed therein may be used in such methods as treatments, diagnosis, drug screening, but does not provide any specific information regarding how each of the different proteins of the invention would by used in such methods. For example, the Specification indicates that the claimed polypeptides as a group are associated with a wide variety of unrelated diseases. However, the Specification only indicates that the polynucleotides or polypeptides of the invention can be used to treat the diseases associated with decreased expression of the polypeptides of the invention and does not provide any more specific information regarding which diseases are associated with the decreased expression of which disclosed protein. Thus, which diseases could be treated with which of the proteins of the present invention? Which diseases could be treated by increasing the amount of the claimed polypeptide and which diseases could be treated by decreasing either the amount or activity of the claimed polypeptide? How is the polynucleotide related to the disease in terms of diagnosis? Would one look for increases or decreases in mRNA, and/or modifications (mutations, deletions, insertions)? In addition the Specification does not teach what effects these modifications would have.

There are no working examples of using the claimed polynucleotides or polypeptides in any methods of treatment, diagnosis, or drug screen.

In a sequence search, sequences identical to SEQ ID NOs: 6 and 12 and the reverse translation of SEQ ID NO:6 were not found in the prior art. Thus, it appears that the state of the prior art is such that proteins of the invention and polynucleotides encoding them were unknown. Caplan et al. (Mol. Biol. Cell (1993) 4 : 555-563) indicates that the functions of the eukaryotic homologous of the dnaJ family were diverse and not completely characterized at the time of the invention. Caplan et al. does not indicate that there were any known methods of using any members of the family in methods of treatment or diagnosis or drug screening.

The relative skill of those in the art is such that the proteins of the invention could be expressed using the claimed polynucleotides and the function of the proteins could be elucidated with further research. However, given the guidance provided in the Specification and in the prior art, the skilled artisan would not be able to predict with any expectation of success, the relationship of the claimed polynucleotide or protein it encodes with any disease or disorder. Thus, the art of using a cDNA encoding a protein with unknown function to treat a disease when the relationship of the encoded protein with the disease is unknown is highly unpredictable.

A large quantity of experimentation would be required to determine the physiological role of the protein encoded by the claimed polynucleotide, to determine what parts of the sequence can be deleted and to determine the relationship of the polynucleotide to a disease in order to use it in any methods of treatment or diagnosis.

To use the claimed polynucleotides or proteins would not require merely a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the characterization of the physiological role of the encoded protein and its relationship to a specific disease or disorder. It is this additional characterization of the polynucleotide and encoded protein that constitutes undue experimentation.

Claims 2, 4, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry , is whatever is now claimed" (see page 1117).

A review of the language of the claims indicates that these claims are drawn to a genus, i.e., polynucleotides with 70% identity to SEQ ID NO:12 or to polynucleotide encoding SEQ ID NO:6 (clms 4 and 10), and variants having at least 90% identity to SEQ ID NO:6.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a

substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA...requires precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, i.e. the polynucleotide of SEQ ID NO:12 or the polypeptide of SEQ ID NO:6. The disclosure of a single disclosed species may provide adequate written description of a genus when the species disclosed is representative of the genus. However, the present claims encompass numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises polynucleotides with 70% identity to SEQ ID NO:12 or to polynucleotide encoding SEQ ID NO:6 (clms 4 and 10), or variants having at least 90% identity to SEQ ID NO:6 (clm 2). The specification does not "clearly

allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
July 20, 2004

Supervisory Jon P. Weber, Ph.D.
Primary Examiner